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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,791	10/25/2000	Joan M. Robbins	480124.407	4714

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EXAMINER	
LACOURCIERE, KAREN A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 06/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/696,791	Applicant(s) ROBBINS ET AL.	
	Examiner Karen Lacourciere	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-105 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-105 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4)☐ Interview Summary (PTO-413) Paper No(s). _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 12, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 1 alpha and beta, classified in class 514, subclass 44.

II. Claims 1-8, 12, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 2, classified in class 514, subclass 44.

III. Claims 1-8, 12, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 6, classified in class 514, subclass 44.

IV. Claims 1-8, 12, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 8, classified in class 514, subclass 44.

V. Claims 1-8, 12, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a

ribozyme which cleaves RNA encoding interferon gamma, classified in class 514, subclass 44.

VI. Claims 1-8, 12, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding tumor necrosis factor, classified in class 514, subclass 44.

VII. Claims 1-8, 13, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 1, classified in class 514, subclass 44.

VIII. Claims 1-8, 13, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 2, classified in class 514, subclass 44.

IX. Claims 1-8, 13, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 3, classified in class 514, subclass 44.

X. Claims 1-8, 13, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 9, classified in class 514, subclass 44.

XI. Claims 1-8, 11, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding Cyclin B1, classified in class 514, subclass 44.

XII. Claims 1-8, 11, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding Cyclin D, classified in class 514, subclass 44.

XIII. Claims 1-8, 10, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cyclin PCNA, classified in class 514, subclass 44.

XIV. Claims 1-9, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cell-cycle dependent kinase CDK1, classified in class 514, subclass 44.

XV. Claims 1-9, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cell-cycle dependent kinase CDK2, classified in class 514, subclass 44.

XVI. Claims 1-9, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme

which cleaves RNA encoding cell-cycle dependent kinase CDK4, classified in class 514, subclass 44.

XVII. Claims 1-8, 14-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding vascular endothelial growth factor, classified in class 514, subclass 44.

XVIII. Claims 1-8, 14-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding platelet derived growth factor, classified in class 514, subclass 44.

XIX. Claims 1-8, 15-17 and 19-36, drawn to a method of treating a proliferative skin disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding a reductase, classified in class 514, subclass 44.

XX. Claims 37-42, 46, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 1 alpha and beta, classified in class 514, subclass 44.

XXI. Claims 37-42, 46, and 49-70, drawn to a method of treating treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 2, classified in class 514, subclass 44.

XXII. Claims 37-42, 46, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 6, classified in class 514, subclass 44.

XXIII. Claims 37-42, 46, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 8, classified in class 514, subclass 44.

XXIV. Claims 37-42, 46, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interferon gamma, classified in class 514, subclass 44.

XXV. Claims 37-42, 46, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding tumor necrosis factor, classified in class 514, subclass 44.

XXVI. Claims 37-42, 47, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 1, classified in class 514, subclass 44.

XXVII. Claims 37-42, 47, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 2, classified in class 514, subclass 44.

XXVIII. Claims 37-42, 47, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 3, classified in class 514, subclass 44.

XXIX. Claims 37-42, 47, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 9, classified in class 514, subclass 44.

XXX. Claims 37-42, 45, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding Cyclin B1, classified in class 514, subclass 44.

XXXI. Claims 37-42, 45, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding Cyclin D, classified in class 514, subclass 44.

XXXII. Claims 37-42, 44, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cyclin PCNA, classified in class 514, subclass 44.

XXXIII. Claims 37-42, 43, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cell-cycle dependent kinase CDK1, classified in class 514, subclass 44.

XXXIV. Claims 37-42, 43, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cell-cycle dependent kinase CDK2, classified in class 514, subclass 44.

XXXV. Claims 37-42, 43, and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cell-cycle dependent kinase CDK4, classified in class 514, subclass 44.

XXXIV. Claims 37-42 and 48-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding VEGF, classified in class 514, subclass 44.

XXXV. Claims 37-42 and 48-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding PDGF, classified in class 514, subclass 44.

XXXVI. Claims 37-42 and 49-70, drawn to a method of treating or preventing scarring by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding a reductase, classified in class 514, subclass 44.

XXXVII. Claims 71-78, 82 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a

ribozyme which cleaves RNA encoding interleukin 1 alpha and beta, classified in class 514, subclass 44.

XXXVIII. Claims 71-78, 82 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 2, classified in class 514, subclass 44.

XXXIX. Claims 71-78, 82 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 6, classified in class 514, subclass 44.

XL. Claims 71-78, 82 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 8, classified in class 514, subclass 44.

XLI. Claims 71-78, 82 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interleukin 10, classified in class 514, subclass 44.

XLII. Claims 71-78, 82 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding interferon gamma, classified in class 514, subclass 44.

XLIII. Claims 71-78, 82 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding tumor necrosis factor, classified in class 514, subclass 44.

XLIV. Claims 71-78, 83 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 1, classified in class 514, subclass 44.

XLV. Claims 71-78, 83 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 2, classified in class 514, subclass 44.

XLVI. Claims 71-78, 83 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 3, classified in class 514, subclass 44.

XLVII. Claims 71-78, 83 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding matrix metalloproteinase MMP 9, classified in class 514, subclass 44.

XLVIII. Claims 71-78, 81 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a

ribozyme which cleaves RNA encoding Cyclin B1, classified in class 514, subclass 44.

XLIX. Claims 71-78, 81 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding Cyclin D, classified in class 514, subclass 44.

L. Claims 71-78, 80 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cyclin PCNA, classified in class 514, subclass 44.

LI. Claims 71-78, 79 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cell-cycle dependent kinase CDK1, classified in class 514, subclass 44.

LII. Claims 71-78, 79 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cell-cycle dependent kinase CDK2, classified in class 514, subclass 44.

LIII. Claims 71-78, 79 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding cell-cycle dependent kinase CDK4, classified in class 514, subclass 44.

LIV. Claims 71-78 and 84-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding VEGF, classified in class 514, subclass 44.

LV. Claims 71-78 and 84-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding platelet derived growth factor, classified in class 514, subclass 44.

LVI. Claims 71-78 and 85-105, drawn to a method of treating a proliferative eye disease by administering a ribozyme or vector ending a ribozyme which cleaves RNA encoding a reductase, classified in class 514, subclass 44.

Applicant should note, claim 18 is improperly dependent, because it depends on claim 18, and it is not possible to determine what method is being claimed, therefore, claim 18 has not been included in any of the groups set forth in this restriction.

Claims 1-8, 15-17 and 19-36 are generic to groups I-XIX. Claim 12 is generic to groups II-VI. Claim 13 is generic to groups VII-X. Claim 11 is generic to groups XI and XII. Claim 9 is generic to groups XIV-XVI. Claim 14 is generic to groups XVII and XVIII. Claims 37-42 and 49-70 are generic to groups XX to XXXVI. Claim 46 is generic to groups XX-XXV. Claim 47 is generic to groups XXVI-XXIX. Claim 45 is generic to groups XXX and XXXI. Claim 43 is generic to groups XXXIII-XXXV. Claim 48 is generic to groups XXXIV and XXXVI. Claim 82 is generic to groups XXXVII-XLIII.

Claim 83 is generic to groups XLIV-XLVII. Claim 81 is generic to groups XLVIII and XLIX. Claim 79 is generic to groups LI-LIII. Claim84 is generic to groups LIV and LV. These generic claims will only be examined to the extent that they read on the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XIX and XX-XXXVI and XXXVII-LVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods of treatment which are not disclosed as capable of use together and have biologically different effects. Each of the inventions of Group I-XIX are drawn to methods of treatment wherein the effect of the method is a treatment for a proliferative skin disease and the method is performed on a patient with a proliferative skin disease. This is different than each of the methods of Groups XX-XXXVI, which are drawn to methods of treating or preventing scarring, which have the effect of treating or preventing scarring and are performed on a patient with a scar or a condition which has the potential to result in a scar. These methods are all different than the methods of each of groups XXXVII-LVI, which are drawn to methods of treating a proliferative eye disease, which have the effect of treating a proliferative eye disease and are performed on a patient with a proliferative eye disease. Each of these methods would require a separate and distinct search for treatments for different diseases and would have methods with materially different method steps, for example, each method would

require treatment for a different type of patient and would require administration to different locations in the body and potentially different formulations for the compositions administered.

Inventions of each of groups I to XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods of treatment that are not disclosed as capable of use together and have different modes of operation. Each of the methods is drawn to a method of treating a proliferative skin disease wherein the treatment is effected by inhibiting the expression of biologically distinct target molecule. Each method involves materially different method steps, wherein each of the methods uses a ribozyme targeted to a different sequence and is structurally different with respect to the sequence, based on the sequence of the target molecule. The different target molecule, and the structurally distinct ribozymes (with respect to sequence) used in each of these methods, results in a separate and distinct search for each of the methods of groups I to XIX.

Inventions of each of groups XX to XXXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to

materially different methods of treatment that are not disclosed as capable of use together and have different modes of operation. Each of the methods is drawn to a method of treating or preventing scarring wherein the treatment is effected by inhibiting the expression of biologically distinct target molecule. Each method involves materially different method steps, wherein each of the methods uses a ribozyme targeted to a different sequence and is structurally different with respect to the sequence, based on the sequence of the target molecule. The different target molecule, and the structurally distinct ribozymes (with respect to sequence) used in each of these methods, results in a separate and distinct search for each of the methods of groups XX to XXXVI.

Inventions of each of groups XXXVII to LVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially different methods of treatment that are not disclosed as capable of use together and have different modes of operation. Each of the methods is drawn to a method of treating a proliferative eye disease wherein the treatment is effected by inhibiting the expression of biologically distinct target molecule. Each method involves materially different method steps, wherein each of the methods uses a ribozyme targeted to a different sequence and is structurally different with respect to the sequence, based on the sequence of the target molecule. The different target molecule, and the structurally distinct ribozymes (with respect to sequence) used in

each of these methods, results in a separate and distinct search for each of the methods of groups XXXVII to LVI.

Because these inventions are distinct for the reasons given above and the search required for each group is distinct, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Friday 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere PATENT EXAMINER
TC 1600
Karen A. Lacourciere
June 18, 2002